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Center for Medicaid and State Operations

INFORMATIONAL SUPPLEMENT

Medicare, Medicaid, and CLIA Programs: Statutory and Regulatory Requirements Related to Laboratory Participation in Proficiency Testing and the Availability of Proficiency Testing Programs in Cytology

A. Introduction

CMS or its approved accreditation organizations routinely survey laboratories performing cytology testing biennially. In addition to these surveys, the CLIA statute requires that individuals performing cytology examinations be tested for their proficiency. Specifically, at Section 353(f)(4)(B)(iv) of the statute, the Secretary is required to perform a "periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions."

The periodic confirmation and evaluation of an individual's proficiency or their ability to interpret gynecologic cytology preparations accurately, has presented implementation problems for CMS, CDC and the cytology community. The current requirements for cytology proficiency testing are found at 42 CFR Part 493, published February 28, 1992.

Implementation of cytology proficiency testing has taken an extended period of time due to the absence of qualified national proficiency testing organizations, an insufficient number of referenced cytology testing materials, and significant technical difficulties. Currently, there are two CMS-approved cytology proficiency testing programs in the country for 2005 and we anticipate the approval of additional programs in 2006.

This approval demonstrates CMS' continued dedication and commitment to improve one of the principal issues on women's health, that is, accurate and reliable Pap smear results. With the initiation of cytology proficiency testing on a national basis, CMS has implemented every provision of the CLIA law.

We may continue to add inquiries to this Informational Supplement, as necessary.

B. Background and History

B1. What is "CLIA"?

"CLIA" is the acronym used to refer to the Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578. CLIA regulates facilities that perform tests for health purposes on human specimens. In an effort to establish quality standards for all such laboratories and to ensure the accuracy and reliability of patient test results, the Congress decided that virtually all laboratories would be subject to CLIA. Under that authority laboratories must apply for and maintain an appropriate CLIA certificate in order to operate. Certificates are issued upon submission of an acceptable application and payment of the applicable certificate fee.

B2. Does CLIA require proficiency testing for individuals who screen Pap smears?

Yes. Congress explicitly provided for the ". . . periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions,"

Under this authority, CMS set forth final regulations on, among other things, cytology proficiency testing in the February 28, 1992 *Federal Register.* Following a comment period, these regulations became effective on September 1, 1992. These cytology proficiency testing requirements remain in effect to date.

B3. Why was the Clinical Laboratory improvement Act of 1967 (CLIA'67) revised – especially in regards to cytology?

The impetus behind the promulgation of CLIA was Congress' realization that there were significant problems in, among other things, enforcing compliance with CLIA'67 standards, ineffective proficiency testing, inadequate oversight for cytology testing, and the proliferation of unregulated laboratories.

CLIA'67 did not regulate all laboratories performing testing on gynecologic specimens. It did not provide for a limit on the number of Pap smears that could be examined by an individual in a 24-hour period. Consequently, a number of "Pap Mills" appeared that produced Pap smear results that were erroneous and life threatening. (There is a direct relationship between a cytology test finding and the diagnosis of a specific clinical disease. Gynecologic cytology specimens are frequently the first indication of cervical cancer.) Congress promulgated CLIA to resolve these and other concerns.

The Centers for Medicare & Medicaid Services (CMS) has been delegated the responsibility for administering the CLIA program. Currently, there are 3,800 laboratories certified in the subspecialty area of cytology.

B4. Are these cytology proficiency testing regulations new?

No. CLIA included statutory requirements for cytology proficiency testing when it was signed into law by President Reagan on October 31, 1988. The regulations implementing these statutory requirements were published in the *Federal Register* on February 28, 1992 and became effective on September 1, 1992.

C. Proficiency Testing Program Contacts

C1. What are the names of the approved cytology proficiency testing programs for 2005, how can I contact them, and where can I find information about them?

The names and contact information of the two CMS-approved cytology proficiency testing programs in 2005 are listed below:

State of Maryland Cytology Proficiency Testing Program
Maryland Department of Health and Mental Hygiene
Office of Health Care Quality – Laboratory Care
Spring Grove Hospital – Bland Bryant Building
55 Wade Avenue
Catonsville, Maryland 21228
Phone Number: (410)402-8028

Midwest Institute for Medical Education, Inc.
9550 Zionsville Road
Suite 110
Indianapolis, Indiana 46268
Phone Numbers: (317)876-4169, (800)575-2342
www.mimeonline.com, www.cytoquest.com, or www.mimeinc.org/

C2. Will additional cytology proficiency testing programs be approved for testing in 2005?

CMS anticipates receiving additional cytology proficiency testing program applications in 2005 for approval of cytology proficiency testing programs to begin testing in calendar year 2006; however, laboratories and individuals, as appropriate, must choose one of the two programs listed above for testing in 2005.

D. Regulatory Requirements

D1. Who must take this proficiency test?

All individuals (physician and cytotechnologists) who examine Pap smears must enroll and participate in one testing event annually.

D2. If I only screen non-gynecologic cytology specimens, must I participate in this cytology proficiency test?

At the present time, only those individuals who examine gynecologic specimens must enroll and participate.

D3. What is considered a passing score on a proficiency test?

A passing score on all cytology proficiency tests is 90%.

D4. Will my proficiency test be unannounced or will I know in advance when to anticipate my proficiency test?

Under most circumstances, your Cytology proficiency test will be an announced event. Proficiency testing programs are required to notify laboratories at least 30 days prior to testing for announced proficiency testing. Approved programs must also have the capability of providing unannounced proficiency testing when requested by CMS.

D5. What happens if I miss the testing event in my laboratory?

If a test is missed due to an unexcused absence, the individual receives a test score of "0".

If the test is missed for an excused absence, laboratories must contact the proficiency testing program to determine when and where the make-up examination will take place. Examples of "excused" absences include prior scheduled leave, natural disasters, hospitalization, death in the family, etc.

D6. If I fail a proficiency test, will I have to stop screening Pap smears?

Individuals have multiple opportunities to take the proficiency test and any retest, if necessary. Initially, individuals are required to take a 10–slide test, provided in sets.

- If an individual passes the first 10-slide test, he/she has successfully participated for the year and need not be tested again until the following year.
- If the individual fails the first 10-slide test, he/she is allowed to take a 10-slide retest within 45 days after notification of test failure.

- When an individual passes the second 10-slide test, he/she has successfully participated for the year and need not be tested again until the following year.
    - If the individual fails the 10-slide retest:
        - The individual must obtain documented, remedial training in the area of test failure, which will be noted on the test results letter.
        - All Pap smears screened by the individual subsequent to the notification of failure must be reexamined, and
        - The individual must successfully participate in a 20-slide proficiency test.
- If the individual fails the 20-slide test:
    - He/she must cease examining Pap smears immediately upon notification of failure;
    - The individual must obtain at least 35 hours of documented, formally structured, continuing education in diagnostic Cytopathology which focuses upon the examination of gynecologic cytology; and
    - The individual must successfully participate in another 20-slide proficiency test.
    - This final cycle would continue until the individual successfully participates in another 20-slide proficiency test.

Please see Attachment A at the end of this document for an overview of the testing process.

D7. How much time will I have to take a 10-slide test? A 20-slide test?

Each individual (physician or cytotechnologists) will be allowed a total of 2 hours to complete a 10-slide test and 4 hours to complete a 20-slide test.

D8. How will cytotechnologists and physicians be tested?

Every individual will be tested independently. Each cytotechnologist will receive a test set of referenced slides, examine each slide, identify the diagnostic areas in the same manner as they do patient specimens (by dot or circle), and write their diagnosis on their score sheet. Physicians who perform any primary screening (screen slides which have not been pre-screened by a cytotechnologists) must be tested in the same manner as a cytotechnologist. Physicians who examine slides after they are pre-screened by a cytotechnologist may choose to screen a set of test slides that have been previously screened and dotted by cytotechnologists or they may examine a set of slides that have not been previously screened and dotted. If the physician chooses to examine a pre-screened set, the cytotechnologist's diagnosis will accompany the test set.

D9. Who will receive a copy of my test results?

CMS will receive all testing results from the CMS-approved Proficiency Testing Program . The laboratory director of your laboratory will receive a summary of

the test results for all the participants in the laboratory within fifteen days after the proficiency testing. The notification will include whether each individual passed or failed the test, their score, and, if appropriate, the area of failure. In addition, each participant will receive a letter with their individual test results, including whether he/she passed or failed the test, their score, and, if appropriate, the area of failure. If an individual works at more than one laboratory, a copy of the test results will be sent to each laboratory director where the individual is employed.

D10. How are the slides referenced by the proficiency testing program?

All slide preparations must have 100% consensus agreement among a minimum of three physicians certified in anatomic pathology. Additionally, non-negative slide preparations must be confirmed by tissue biopsy, either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology.

D11. Will the test sets be comparable?

Yes, each of the test sets, whether 10-slide or 20-slide, will be comparable. Each test set must include at least one slide representative of each of the diagnostic categories listed in the CLIA regulations. Test sets must also be equivalent to each other. Several times a year, each slide must be evaluated for staining, breakage, and diagnostic agreement by the CMS-approved Proficiency Testing Program.

D12. What diagnostic categories are used in the test sets?

The diagnostic categories for Pap smears in the test sets include at least one slide from each of the following categories:

- Unsatisfactory samples (i.e., scant cellularity, air drying, and obscuring material (blood, inflammatory cells or lubricant));
- Normal or Benign Changes (i.e., normal, negative, or otherwise within normal limits, infections other than Human Papilloma virus (HPV) (e.g., *Trichomonas vaginalis*, changes or morphology consistent with *Candida* spp., *Actinomyces* spp., or *Herpes simplex* virus),
- Low Grade Squamous Intraepithelial Lesions – includes: Cellular changes associated with HPV, Mild Dysplasia/CIN-1,
- High Grade Squamous Intraepithelial Lesion and Carcinoma – includes moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in-situ/CIN-3, Squamous Cell Carcinoma, Adenocarcinoma and other malignant neoplasms.

D13. Are cytotechnologists and physicians scored the same way?

No. Cytotechnologists and physicians are not scored the same way. Physicians are scored more stringently because they are ultimately responsible for all diagnoses made in the laboratory.

For the 10-Slide Test, the scoring grids are listed below:

Cytotechnologists:

	Participant Diagnosis			
	A	B	C	D
Correct Diagnosis				
A	10	0	**5**	**5**
B	5	10	**5**	**5**
C	5	0	10	**10**
D	0	-5	**10**	10

Technical Supervisors:

	Participant Diagnosis			
	A	B	C	D
Correct Diagnosis				
A	10	0	**0**	**0**
B	5	10	**0**	**0**
C	5	0	10	**5**
D	0	-5	**5**	10

The highlighted areas on the grids demonstrate those diagnostic categories where the cytotechnologist's and technical supervisor's score would differ.

To determine the final score of a testing event, each slide is given a numerical value, as specified on the scoring grids. Cytotechnologists receive a score based on the "Cytotechnologist Grid" and the Technical Supervisor's score is based on the "Technical Supervisor Grid". The Cytotechnologist's and Technical Supervisor's diagnosis can be found along the X-axis. The Proficiency Testing Program diagnosis, based upon 100% consensus of at least 3 physicians board certified in anatomic pathology and tissue biopsy confirmation of cases in the premalignant and malignant categories can be found along the Y-axis. Both Cytotechnologists and Technical Supervisors begin with a score of zero. Points are accumulated based on the accuracy of their diagnosis to the diagnosis specified by the Proficiency Testing Program.

D14. If I miss a high-grade lesion or a cancer, will I pass the test?

No. Individuals (cytotechnologists or physicians) will not obtain a passing score if a slide determined by the proficiency testing program to exhibit a high-grade lesion or cancer is identified as "Normal or Benign Changes" during the testing event.

D15. What would happen in a laboratory if the cytotechnologist passes the test and the technical supervisor fails the test?

In this instance, the cytologist would have completed their testing for that year under CLIA, and the technical supervisor will need to be retested as described in Question C6.

D16. May I enroll in another cytology proficiency testing program when one becomes available?

Individuals must remain in the CMS-approved cytology proficiency testing program for one calendar year. Participants will be provided with their own unique Proficiency Testing Registration Number. This number will be used to identify each individual's enrollment. After that time, individuals are welcome to participate in any CMS-approved program.

E. Enrollment and Testing

E1. What are the initial cytology proficiency testing enrollment requirements?

Beginning in 2005, every cytotechnologist and pathologist examining gynecologic cytology specimens must be enrolled in a CMS-approved Cytology Proficiency Testing Program and take a proficiency test. CMS strongly recommends that laboratories enroll in one of the two CMS-approved Cytology Proficiency Testing Programs for 2005 as soon as possible.

E2. Where do the dates specified in the Survey and Certification Letter (SC05-11) released by CMS on December 16, 2004 come from?

CMS regrets that some confusion has arisen in regard to the dates by which laboratories must enroll and be tested in a CMS-approved cytology proficiency testing program. Laboratories generally must meet the regulatory deadline for enrollment and participation in an annual testing event, which may include retesting where necessary. Testing must be completed by December 31 of the testing year in order to comply with regulatory provisions. The dates listed in the Survey and Certification Letter were established as dates that laboratories must meet in order to avail themselves of CMS' plans to utilize its enforcement discretion to hold in abeyance any potential sanction for as long as possible. The Survey and Certification Letter identifies internal deadlines that CMS will use when deciding whether to initiate sanctions against laboratories that fail to enroll in a CMS-approved Cytology Proficiency Testing program and complete initial testing by the close of 2005.

CMS strongly encourages laboratories to enroll in one of the CMS-approved Cytology Proficiency Testing programs as soon as possible.

E3. Where do I take the Cytology proficiency test?

Proficiency testing may occur on-site in your laboratory or at an alternate site at least once during each calendar year.

Contact the Proficiency Testing Program in which you have enrolled for specific requirements and procedures.

E4. I screen slides on the night shift (4:00 PM - 12:00am). When will I be tested?

To the extent practicable, testing should take place under your normal working conditions. Laboratories should contact their Proficiency Testing Program for specific information on this issue.

E5. If I examine only liquid based specimens at my laboratory, will I be required to take my proficiency testing with conventional Pap smear?

A CMS-approved Proficiency Testing Program will offer testing materials that are prepared in a similar manner to the patient specimens routinely examined.

Contact the CMS-approved Proficiency Testing Program in which you have enrolled for specific requirements.

E6. What happens if I work at more than one laboratory? Must I take the test at each laboratory where I am employed?

No. If you work at more than one laboratory, you will be required to indicate one laboratory, prior to the first testing event, as the primary laboratory where you will be tested. All of the laboratories, however, must ensure that you participated in the required annual testing in order to meet their regulatory duties.

E7. Will Locum tenens and Temporary Employees in laboratories also need to be tested?

Yes. Any individual, including a Locum tenens or temporary employee, who examines Pap smears must participate in annual testing and score at least 90%.

E8. Who will proctor the proficiency test?

The CMS-approved Proficiency Testing Program will provide guidance and requirements for individuals who will proctor the proficiency test.

Contact the CMS-approved Proficiency Testing Program in which you have enrolled for specific information on proctors.

E9. What should I do if I get a test set with a broken slide?

The test proctor should be notified immediately upon discovery of a broken slide. Proctors have specific protocols to follow when this occurs. The laboratory will be held financially responsible for any slides broken during testing.

E10. If the laboratory hires a new employee just prior to the scheduled proficiency test, can this individual also take the scheduled proficiency test?

Please call the Proficiency Testing Program for specific procedures.

E11. If I fail a test or retest, can I take the retest in my laboratory?

The Proficiency Testing program will have options for retesting. Please contact the program in which you are enrolled for additional information.

E12. How many individuals can be tested with one test set?

The Proficiency Testing Program will determine how many test sets are needed to test all individuals in the laboratory.

E13. Who in the laboratory can reexamine the Pap smears that were read by someone who has failed the first retest?

A qualified individual who has obtained a passing score in the current year is eligible to reexamine Pap smears after someone has failed.

E14. What should I do if I see someone sharing test results during the test?

Discussion during and after the course of testing is prohibited. Every individual who participates in a proficiency test must sign an attestation statement that they have examined the test set slides independently and did not share their results either during or after testing. If a participant observes results sharing, the proctor must be notified of the situation. The proctor will contact the proficiency testing program immediately. The program will notify CMS.

E15. Will instructors, researchers, and individuals who perform internal quality control or quality assessment functions be required to participate in cytology proficiency testing?

Those individuals (instructors and researchers) who do not examine gynecologic patient specimens for the purpose of making a diagnosis or providing any information to be used toward a diagnosis are not required to participate in gynecologic cytology proficiency testing. However, those individuals who review patient specimens during the course of their jobs (internal quality control/quality assessment) where a diagnosis might be changed because of their review must participate in cytology proficiency testing.

F. Appeals

F1. Is there a procedure to be followed when an individual disagrees or questions their test results?

The proficiency testing program should be contacted directly to discuss scoring questions. All approved programs must have a scientifically defensible process for determining the correct result for each challenge offered.

G. Enforcement

G1. Will CMS monitor the participation of individuals in a CMS-approved Cytology Proficiency Testing Program?

Yes. CMS will monitor the enrollment and participation of cytotechnologists and pathologists in a CMS-Approved Cytology Proficiency Testing Program.

G2. What happens if I fail my proficiency test and my laboratory does not take the appropriate corrective actions to help me pass the retest?

If the laboratory where you are tested does not ensure that you participate in an annual testing event, or that you are retested or the laboratory fails to take the appropriate remedial actions as described in Question D6, CMS will initiate intermediate sanctions against the laboratory or limit the laboratory's CLIA certificate for cytology, and if applicable, terminate the laboratory's Medicare approval for cytology. CMS suggests that laboratory management be made aware of the consequences of the laboratory's failure to be enrolled and tested in a CMS-Approved Cytology Proficiency Testing Program, and take appropriate corrective actions in the event of test failure.

H. Confidentiality

H1. How will CMS monitor the participation of the individuals enrolled in the proficiency testing program?

CMS has developed a System of Records, secured under the Privacy Act of 1974; the Federal Information Security Management Act of 2002; et.al. that will be used to monitor each individual's enrollment and participation, record individual results, and ensure compliance with CLIA requirements. CMS will also participate in unannounced monitoring of proficiency testing events.

A notice in the *Federal Register* was published on January 14, 2005 with a description of the New System of Records proposed by CMS.

H2. If I fail the first proficiency test, will the information be public to anyone?

Every proficiency testing result will be reported to CMS, the cytotechnologist or pathologist who took the test, the laboratory director in the laboratory where the test was taken, and every other laboratory where the cytotechnologist or pathologist is employed. CMS will not release any test scores until after the completion of the entire testing process.

I. Fees

I1. What is the enrollment fee to participate in this proficiency testing program?

The proficiency testing program determines all relevant charges for laboratory participation based on the operational costs as a private non-profit organization or a Federal or State agency or entity acting as a designated agent for the State.

I2. If I fail the test in my laboratory and have to travel to be retested, who will pay the expenses?

Financial obligations for enrollment and testing are the responsibility of the laboratory. Retesting is subject to individual policies of the laboratory.

J Overview

J1. In summary, what must laboratories and individuals do each year in order to comply with the cytology proficiency testing regulations?

- Laboratories must ensure that each cytotechnologist and pathologist examining gynecologic cytology preparations is enrolled in a CMS-approved Cytology Proficiency Testing program.
- Cytotechnologists and pathologists who are not routinely employed in a laboratory must contact a CMS-approved Cytology Proficiency Testing Program directly to enroll in an approved program.
- Cytotechnologists and pathologists must be tested once per year and score at least 90%.
- Laboratories must ensure that individuals who fail a test are retested within the required timeframes.
- Laboratories must take the appropriate remedial actions for any individuals who fail a cytology proficiency test event.
- Individuals who are not routinely employed in a laboratory should contact CMS for further information.

ATTACHMENT A

Overview of Testing Process for Individuals Examining Pap Smears